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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,793	10/01/2001	Benedito Da Silva	TIN-0017	5160

23413 7590 11/26/2002

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BLOOMFIELD, CT 06002

EXAMINER
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COOK, REBECCA

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 11/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/868,793

Applicant(s)

DA SILVA, BENEDITO

Examiner

Rebecca Cook

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 September 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-26 is/are pending in the application.
- 4a) Of the above claim(s) 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1614

Newly submitted claim 26 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: it is directed to a composition that can be used in other methods such as to treat skin aging.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 26 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The amendment filed 9/30/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: on page 2, lines 43-47, the substitute specification recites that the active compound comes in an aqueous solution made of 15% water in 85% acid and that the ideal composition is 70% 1,2,3-propanetriol and 30% 1,2,-propanodiol. No support is seen in the originally filed disclosure for this.

Applicant is required to cancel the new matter in the reply to this Office Action.

Applicant is advised that should claim 11 be found allowable, claim 23 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Art Unit: 1614

It is inherent in claim 1 that the alpha-hydroxypropionic acid and pharmaceutically acceptable vehicle are in a form that is adapted to be administered to the intended subject.

The disclosure is objected to on page 2, lines 43-44. The intent of the recitation "an aqueous solution made of 15% water in 85% of acid" is confusing, since claim 13 recited 85 vol. % aqueous solution. It thereby appears that the intent is that the compound comes in a 15% to 85% aqueous solution.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: no support is seen in the specification for the "concentration of 0.2-10 vol %" in claim 11; "high airway diseases" in claims 15 and 16; "nasal releaser" in claim 17; "clearing agent of nasal cavities and cheekbones" in claim 19.

The disclosure is objected to because of the following informalities: in claim 11, line 5 the word "is" is missing. The claim would be more clear if it read "wherein the alpha-hydroxypropionic acid is in a concentration."

Appropriate correction is required.

Claims 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No support is seen in the originally filed disclosure for the amount of alpha-hydroxypropionic acid of claim 13 and the 70 ml of 1,2,3-propanotril and 30 ml of 1,2-propanodiol of claim 14.

Art Unit: 1614

Claims 11-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating sinusitis and rhinitis, does not reasonably provide enablement for treating all upper respiratory disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification does not disclose that the instant method can be used to treat nasal polyps, for example. Amending the claim to recite "sinusitis and rhinitis" and canceling claim 25 will overcome this rejection.

Claims 15-19, 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 15 and 16 it is not clear what the recitation "high airway" diseases means and what conditions it is intended to include. Applicant's argument that it means the upper airway system is not persuasive, since it is not an art recognized term and is not defined in the specification.

In claims 15 and 24 the word "includes" renders the claim indefinite because it is unclear whether the limitations following the word are part of the claimed invention. See MPEP 2173,05(d). Applicant's argument that it refers to respiratory diseases not limited to sinusitis and high airway diseases is not persuasive, since it is not clear what other diseases are intended to be included.

In claim 19 it is not clear what is meant by the recitation "clearing agent of nasal cavities and cheekbones." Applicant's argument that it pertains to the removal of

Art Unit: 1614

undesired or disease-causing agents from the nasal cavities and cheekbones is not persuasive, since it is not an art recognized recitation and is not defined in the specification.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 27 21 014. The reference (abstract, lines 1-7) discloses that alpha-hydroxy propionic acid can be used to treat allergies and viral diseases. The instant claims differ over the reference in recited amounts and specific solvents. However, in the absence of a showing of unexpected results, once a method of using a compound is known it would be obvious to one of ordinary skill in the art to determine the optimum amount and solvent.

In view of applicant's argument the rejection under 35 U.S.C. 103(a) to JP 6317323 A is withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone

Application/Control Number: 09/868,793

Page 6

Art Unit: 1614

number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
REBECCA COOK  
PRIMARY EXAMINER  
GROUP 1200 1614

November 21, 2002